Frequently Asked Questions - Certificates

What are the certificate types?

- Certificate of Waiver (COW) Issued to a laboratory that performs only CLIA waived tests.
- Certificate for Provider Performed Microscopy (PPM) Procedures Allows the facility to perform only CLIA waived and specific microscopy PPM tests.
- Certificate of Registration Issued to allow the laboratory to perform CLIA waived, PPM and non-waived (moderate or high complexity) testing until the laboratory is surveyed (inspected). Once the laboratory is inspected and found in compliance, a final certificate of Compliance or Accreditation is issued.
- Certificate of Compliance (COC) Issued once the laboratory is inspected and found in compliance. This type of certificate allows the laboratory that performs CLIA waived, PPM and non-waived (moderate and/or high complexity) testing. Inspection is conducted by the CLIA Program.
- Certificate of Accreditation (COA) Issued once the laboratory is inspected and found in compliance. This type of certificate allows the laboratory that performs CLIA waived, PPM and non-waived (moderate and/or high complexity) testing. Inspection is conducted by the laboratory selected CMS approved accredited agency- AABB, AOA, ASHI, COLA, CAP, or JCAHO.

What is the cost for a CLIA certificate? How long are they effective?

All types of certificates are effective for two years and renewable. CLIA waived certificate is \$150 (every two years), CLIA PPM certificate is \$200 (every two years), and CLIA compliance or accredited (every two years and fee is based on number of tests and specialties).

How do I apply for a CLIA certificate?

Complete a CLIA application (Form CMS-116), a CLIA Ownership Information form and a List of Tests
Performed form (available on this website under FORMS) or by visiting the CMS CLIA website. Mail the
original signed completed application along with The CLIA Ownership Information form and the List of
Tests Performed form to the Nebraska CLIA Program, DHHS Division of Public Health, Licensure Unit –
Acute Care Facilities, P O Box 94986, Lincoln, NE 68509-4986 or call the Nebraska CLIA Program for
assistance at 402-471-4363.

What additional documents are required for a Certificate of CLIA waived, PPM, compliance and accreditation?

Along with the CMS-116 form, the List of Tests Performed and CLIA Ownership Information form are required to be completed in Nebraska.

How long does it take to get my CLIA certificate?

Once the application is received and approved it will be entered into a Federal database. Approximately 10 days to two weeks later, a fee coupon will be generated by the CLIA federal program and sent to your designated mailing address. Once payment is received, a certificate will be sent (approximately 10 days to two weeks). The average time to receive your CLIA Certificate is four to six weeks.

NOTE: If your application is for a CLIA certificate of compliance or accreditation, you will receive a certificate of registration. This type of certificate is temporary; however, once you are inspected and found in compliance, a new bill will be sent to your facility and, once paid, a new certificate will be issued.

Can I pay the certificate fee by phone or credit card? And where do I send the payment?

NOTE: Payment by Internet or credit card requires a CMS-issued CLIA number. New applicants must wait until you receive your user fee invoice from CMS; your CLIA number will be on the invoice.

Payments by credit card or Internet can be accepted by following these instructions:

Go to www.pay.gov

- In the search engine on the Pay.gov page, type "CLIA" and click Search.
- Under "CLIA Laboratory User Fees," click Continue to the Form.
- Follow the steps listed to pay your fee.
- Print your confirmation that payment has been sent and retain it for your records.

If you wish to pay by mail, follow the instructions on the fee coupon attached to the invoice you receive from CMS. Write your CLIA number on the check to ensure it is applied to the correct account, as stubs may become detached during processing.

Where do I mail the application?

Applications can be mailed to: DHHS Division of Public Health, Licensure Unit – Acute Care Facilities, P O Box 94986, Lincoln, NE 68509-4986. CMS requires we have the original signed application form – we do not accept faxed or emailed copies.

How do I renew my CLIA certificate?

Renewal billing coupons for CLIA certificates of wavier, PPM and certificates of accreditation are automatically mailed out beginning six months prior to the current certificate expiration date. Fee coupons for CLIA certificate of compliance renewals are mailed 12 months prior to the current certificate expiration date. You may send your renewal payment by mail or pay online by following the instructions below:

- Go to www.pay.gov.
- In the search engine on the Pay.gov page, type "CLIA" and click Search.
- Under "CLIA Laboratory User Fees," click Continue to the Form.
- Follow the steps listed to pay your fee.
- Print your confirmation that payment has been sent and retain it for your records.

I lost my renewal bill and my CLIA certificate is about to expire. How can I send the payment?

For CLIA waived and PPM certificates, you may renew your certificate by following the instructions below. If you have a certificate of compliance or accreditation, call the Nebraska CLIA Program at 402-471-4363. The Nebraska CLIA Program will need to verify the cost of your bill. Once the cost of your renewal bill is disclosed, follow the steps below.

- Payment can be sent via U.S. Postal Service (NO FedEx or UPS). Mail a check or money order to:CLIA Laboratory Program, P.O. Box 530882, Atlanta, GA 30353-0882
- 2. With your payment, include the name and address of your facility, and write your CLIA number on the FACE of check or money order, as stubs may become detached during processing. If possible, include a copy of the old CLIA certificate. CLIA waived fee is \$150, PPM is \$200.
- 3. Payments by credit card or Internet can now be accepted by following these instructions:
 - o Go to www.pay.gov.
 - o In the search engine on the Pay.gov page, type "CLIA" and click Search.
 - o Under "CLIA Laboratory User Fees," click Continue to the Form.
 - o Follow the steps listed to pay your fee.
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I forgot to renew my certificate and now it has expired. Can I still pay and reactivate my certificate?

You may reactivate your certificate if it is within six months of the expired date by following the instructions below:

- Payment can be sent via U.S. Postal Service (NO FedEx or UPS). Mail a check or money order to: CLIA Laboratory Program, P.O. Box 530882, Atlanta, GA 30353-0882
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My certificate expired more than six months ago. How can I reactivate my certificate?

If the expired date is greater than six months, you will be required to submit a new CMS-116 to the Nebraska CLIA Program. You may request reactivation by selecting the box marked "Other" at the top of page and specify "certificate reactivation." Once your request is processed, a new bill will be sent to your designated mailing address.

I already paid for the renewal of my certificate. When can I expect the new CLIA Certificate?

New certificates are mailed out approximately two weeks before the expiration date on the old certificate.

I have already sent my payment. Why am I getting another bill?

On occasion checks or money orders are lost or misplaced. Check with your bank to see if your check has been cashed. If cashed, call the Nebraska CLIA Program at 402-471-4363.

I sent two renewal payments by mistake. How can I ask for a refund?

For CLIA waived and PPM, refunds are returned automatically; however, it may take up to six months. For refunds on certificates of compliance or accreditation, call the Nebraska CLIA Program at 402-471-4363.

I no longer need my CLIA certificate. Can I cancel the certificate and request a refund?

Unfortunately, there are no refunds, even if the certificate was never used.

Our laboratory is closing and I received a renewal bill. Do I need to pay?

Do not pay the bill. Contact the Nebraska CLIA Program by e-mail or mail and provide an official termination date.

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